IN THE UNITED STATES PATENT OFFICE

Applicant	:	Cheever et al.
Appl. No.	:	09/854,356
Filed	:	May 9, 2001
Title	:	HER-2/NEU FUSION PROTEINS
Grp./A.U.	:	1643
Examiner	:	Lynn Bristol
Docket:	:	CRX113US1

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 CFR 1.132

I, Dr. Jamila Louahed, do hereby declare as follows:

1. I am currently employed by GlaxoSmithKline as Senior Manager and Head Of Serology & Molecular Biology , Cancer Disease Area Program. I am located in Rixensart, Belgium, and am involved in research at GlaxoSmithKline regarding immune response to Her2/Neu proteins.

2. I am an author on the Abstract by Limentani et al., titled 'Evaluation of a recombinant Her2 vaccine: Induction of specific antibodies, T-cells and preliminary activity in metastatic breast cancer patients' and published in the *Journal of Clinical Oncology*, 2006 ASCO Annual Meeting Proceedings, Vol. 24, No. 18S (June 20 Supplement), 2006 at page 631 ("the Abstract").

3. The Abstract reports data from GSK Study ID 719125/002 (Dose Escalation Study in the Adjuvant Setting; National Clinical Trials identifier NCT00058526)) of a recombinant Her2 protein, used as an adjuvant treatment for Stage II or Stage III Her2 positive breast cancer in human patients. The Abstract describes the recombinant Her2 protein as including the extra-cellular domain and part of the intra-cellular domain of Her2.

4. I am also an author on the Poster by Limentani et al. titled 'A recombinant Her2 protein evaluated for cancer immunotherapy: Induction of specific antibodies and T-cells', presented at the 18th EORTC-NCI-AACR Symposium, November 7-11, 2006, Prague, CZ ("the Poster").

5. The Poster reports data from the same clinical study as the Abstract (719125/002) , and also data from a Phase II study of metastatic Her2 positive breast cancer in human patients (GSK Study ID 100633 (National Clinical Trials Identifier NCT00140738)). The

Poster describes the recombinant Her2 protein as including the extra-cellular domain and part of the intra-cellular domain of Her2.

6. I have reviewed the specification of US Patent Application Serial No. 09/854,356, including the 919 amino acid sequence provided at SEQ ID NO:6 for a recombinant Her2 protein.

7. The recombinant Her2 protein referred to in the Abstract and the Poster, and used in both the NCT00140738 and NCT00058526 studies, was the 919 amino acid sequence disclosed as SEQ ID NO:6 in US Patent Application Serial No. 09/854,356.

8. In both the NCT00140738 and NCT00058526 studies the recombinant Her2 protein was administered with AS15 adjuvant. AS15 is a combination of a CpG-containing oligonucleotide (CpG7909), monophosphoryl lipid A, and QS-21 (a saponin derivative).

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jamila Louahed

04/05/2004
Date